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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,623	12/07/2001	John Kung	JBP 576	9719

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PHILIP S. JOHNSON  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/020,623

Applicant(s)

KUNG ET AL.

Examiner

Shahnam Sharareh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12/7/2001, 7/28/2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-29 is/are pending in the application.
- 4a) Of the above claim(s) 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group III, claims 27-29 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that searching of the three groups of claims do not entail a burden upon the Office. This is not found persuasive because mere different classifications of the inventions are *prima facie* evidence of showing the burden to the Office.

The requirement is still deemed proper and is therefore made FINAL.

Claims 24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5. Claims 27-29 are under consideration.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-29 depend on a non-existing claim 32. Accordingly, they lack sufficient antecedent basis as to which claim are the depending. Thus, their scope is not clear.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Simon et al US patent 5,730,972.

The instant claims are directed to methods of applying compositions comprising a lipophilic active agent, a sugar, and a polymeric emulsifier.

Simon et al disclose compositions for combating skin marks comprising at least one sugar such as ascorbyl-2-glucoside, (see abstract, claim 1 and 5). The composition of Simon further comprise a polymeric emulsifier such as Pemulen, a polyethylene alcohol such as polyethylene glycol stearate, and a moisturizing agent such as glycerol (see col 7-9). Simon also teaches the use of a lipophilic adjuvant in his composition (see claim 12). Simon finally discloses methods of using their composition for appropriate protection of skin (claim 17-20). Since method steps of Simon are the same as the instant claim, and Simon employs compositions comprising the same ingredient as those instantly claimed, Simon's methodology inherently anticipates the instant intended use.

4. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Hughes et al US Patent 5,322,689.

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Hughes et al disclose topical aromatic releasing compositions comprising an acrylic polymer (see col 3-4) a polyoxyethylene alcohol such as polyethylene glycol, or even polyhydroxy alcohol such as glycerin or propyl glycols or hexylene glycol (see col 5, and col 7 lines 45-55), and various types hydrophobic active moieties (see col 8-9, col 11 lines 30-65, claims 1-10). Hughes specifically discloses the use of such polymers as Pemulen (a hydrophobically-modified hydrophilic polymer)(see col 4, line 47; col 11, line 60). Hughes also discloses the use of Steareth-20 (see col 4, line 49). Hughes further discloses methods of using their composition (claims 13-17). Since method steps of Hughes are the same as the instant claim, and Hughes employs compositions comprising the same ingredient as those instantly claimed, Hughes' methodology inherently anticipates the instant intended use.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oblong et al US Patent 6,238,678 (Oblong) in view of Simon et al (Simon) US Patent 5,730,972.

The instant claims are directed to methods of use of compositions consisting essentially of a retinoid, an acrylate polymeric emulsifier, and ascorbyl-2-glucoside, a polyoxyethylene alcohol.

Oblong teaches topical administration of emulsions comprising vitamin B and retinoids in combination an antioxidant such as ascorbic acid or ascorbyl esters of fatty acids etc., acrylate/C10-C30 alkyl acrylate cross-polymer such as Pemulen. (see abstract, col 23, lines 4-60; col 27, lines 9-20; col 29, lines 9-13; col 30, lines 51-53; examples 3-4; claims 1-4). Oblong's composition can contain sunscreen. Oblong's compositions do not contain ascorbyl-2-glucoside.

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Simon discloses compositions and methods of applying them for combating skin marks comprising at least one sugar such as ascorbyl-2-glucoside, and a UVA screening agent (see abstract, claim 1 and 5). The composition of Simon et al also comprise a polymeric emulsifier such as Pemulen, a polyethylene alcohol such as polyethylene glycol stearate, a moisturizing agent such as glycerol (see col 7-9; example 3). Simon specifically states that ascorbic acid glucoside is highly water-soluble and is converted to Vitamin C when administered to skin (see col 2, lines 51-60). Simon does not employ retinoids in his compositions.

Both Oblong and Simon teach methods of topical delivery of an active agent, a vitamin C derivative, a polymeric emulsifier and an additional active agent; therefore, their teachings are viewed as being in the same field of endeavor.

Although Oblong do not use ascorbic acid glycosides in their methodology, it would have obvious to one of ordinary skill in the art at the time of invention to modify Oblong's methodology by using the ascorbic acid precursor of Simon et al in place of the ascorbic acid derivative antioxidants of Oblong, because as stated by Simon, the ordinary skill in the art would have expected that the ascorbic acid glycoside convert to ascorbic acid and provide the same properties as do ascorbic acid.

Further, as it is general knowledge in the art, the ordinary skill in the art would have had a reasonable expectation to improve skin aging when administering a retinoid with any agent that would protect the skin from aging, i.e.

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vitamin C derivative (see for example Liu et al US Patent 6,080,393, col 7, lines 25-35 for the general knowledge in the art). Thus, absence of showing unexpected results, substituting the antioxidants of Oblong with its art equivalent, namely ascorbic acid glycoside, would have been *prima facie* obvious.

Furthermore, it would have been within purview of the ordinary artisan to optimize the concentrations of the ingredients by routine experimentation.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400. The examiner can normally be reached on Monday to Friday from 8:30 a.m. to 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Padmanabhan Sreenivasan can be reached on 703-305-1877. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

  
RUSSELL TRAVERS  
PRIMARY EXAMINER

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October 31, 2003